REMARKS

Applicant has noted the rejections set forth in the Office Action mailed February 24, 2003. For the reasons set forth beginning on page 11 of this paper, Applicant respectfully traverses the rejections. Applicant states that the currently amended claims overcome the Office Action rejections.

Pursuant to 37 C.F.R § 1.121(f), Applicant affirms that no new matter has been added to the application in the amended specification or claims, but is intended to only more accurately reflect the invention and better aid in the understanding and comprehension of the claimed device.

Claims 1-11, 13-18 and 20 have been previously withdrawn from consideration as the result of an earlier restriction requirement, but are included in the Claims Listing in Appendix A. Claims 12 and 19 are being amended to a protein detection method. Please also add claims 21 and 22 which depend from claims 12 and 19, respectively, and to not add any new matter.

ARGUMENT

Rejections:

For the following reasons, Applicant respectfully submits that the rejections have been overcome by the amendments set forth herein and requests that the claims be passed to allowance.

The Office Action has rejected claims 12 and 19 under 35 U.S.C.§ 112, first paragraph, as not being enabled and restricted to PSA and Gelonin. Applicant states that by amending the claims to a protein detection method this rejection has been traversed. Specifically, a person of ordinary skill in the art would be able, by following the steps described and using the software provided, to obtain optimal immunobiologically active linear epitope(s) from any globular protein of known sequence, create at least one antisera specifically directed toward the epitope(s) by techniques that are well known in the art, and use the antisera to detect the protein in any given sample. The addition of the information regarding the globular PSA and Gelonin was only an example to illustrate the workings of the invention, but not to restrict the invention to only these proteins.

The Office Action's statement regarding the term "diagnostic" (as referred to in the art as being used for diagnosing a specific pathogen or disease) has also been traversed by amending the claims to a protein detection method. The pending claims currently recite a method of protein detection.

The Office Action has also rejected claims 12 and 19 under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the

subject matter which Applicant regards as the invention. Applicant states that by amending the claims as set forth herein, this rejection has been traversed.

Applicant's method to improve the selection of the optimal immunogenic peptide from a protein of known sequence (see Technical Field, page 1 of the specification) is regarded as part of the invention. The specification provides ample support for this proposition. For example, on page 5 of the specification, first paragraph, the summary of the invention provides: "A further object of this invention is to determine the immunopotency of an epitope and provide a ranking system delineating between dominant and subdominant epitopes."

The claims as currently amended also propose the use of the optimal immunogenic peptide epitope(s) to produce peptides to produce antisera directed toward the protein. This is also supported by the specification. Page 5, third paragraph states,

> "Yet another object of the present invention is to provide for synthetic peptides from a protein having the specific amino acid sequence and length determined by the methods herein that may be used in an immunization regimen..."

Further support for the production of antibodies to the synthesized peptides corresponding to the optimal immunobiologically active epitopes can be found on the first full paragraph on page 18 of the specification, in which it is provided:

> "After identifying the Ho-Hi-Ho epitopes and determining the optimal length of the amino acid residue sequence, peptides can be synthesized that correspond to the exact amino acid sequence and

> length of residues. In turn polyclonal antibodies or monoclonal antibodies can be generated specific for a peptide."

The production of synthetic peptides from a know sequence is well known in the art.

The currently amended claims directed to the detection of proteins utilizing antibodies directed toward the optimal epitope(s) is part of the process in a diagnostic testing procedure, as used by the Applicant, and is supported throughout the specification. Thus it is not new matter. The methods of detecting a protein utilizing immunoassays was included in the broader realm of diagnosis as is evidenced by the last paragraph on page 17 of the specification:

> "The Ho-Hi-Ho epitopes of the present invention can be used in diagnostic tests, such as immunoassays, to detect viruses, microbes and malignant cells. ... Certain preferred immunoassays are various type of enzyme linked immunoabsorbent assays, radioimmunoassay, immunofluorescence and surface plasmon resonance. Immunohistochemical detection using tissue sections is also particularly useful. However, it should be appreciated that detection methods are not limited to such techniques, and Western blotting, dot blotting, FACS analyses and the like may be used."

It is clear by the above statements that Applicant's method to detect proteins by utilizing antibodies directed toward peptides corresponding to the optimal immunobiologically active epitope is supported by the specification.

Applicant has, throughout the specification, used "diagnostic testing" to reflect the ability to detect the protein, as opposed to detecting only pathogens or diseases. Applicant's methods provide an *in silica* method to determine which region of a protein, of know sequence, will elicit an optimal immunogenic response without the need for excessive experimentation. Applicant's methods provide the optimal length, location, and amino acid composition of the optimal epitope. Once this optimal epitope is known, it can be synthesized by techniques well know in the art. Once synthesized, the optimal epitope can be used to generate antibodies by techniques well known in the art. Once the antibodies to the optimal epitope are generated, they can be used to detect the protein.

Applicant's invention is a tool in which individuals of other arts, such as clinicians, will provide the context. Applicant does not intend to claim knowledge and discovery that other researchers provide to the field of diagnosis. Applicant's only claim is a tool that will facilitate the detection of a protein of a known sequence in a given sample.

Applicant respectfully contends that this application is therefore in a condition of allowance and respectfully requests that the application be passed to allowance.

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Respectfully submitted,

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